



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT
Opening Remarks

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DR. GUTMANN: Good morning, everybody. I would ask people to be -- please to be seated. Thank you. I am Amy Gutmann. I am president of the University of Pennsylvania, and chair of the Presidential Commission for the Study of Bioethical Issues. On behalf of myself and our vice chair, Jim Wagner, who is president of Emory University, I would like to welcome you to day two of our meeting.

We welcome in particular our speakers, who have traveled from near and from far to be here: our first speaker from near, and some of our other speakers from far. I look forward to everybody's presentations and our discussions.

Today we will focus on the second part of the President's charge on human subjects protection. This is what we have been calling the forward-looking part of our project. Yesterday, as you know, we had an in-depth discussion of our historical findings on Guatemala, a dark chapter in our history, and also we had a discussion of our ethical analysis of that chapter in our history.

The commission's task in this case is to review current rules for human subjects protection to determine if these rules protect people participating in federally-funded research from harm or unethical treatment. President Obama asked the commission to convene a panel of international experts to seek independent advice on the effectiveness of current U.S. rules and international standards for the protection of human subjects in scientific studies that are supported by the U.S. Government.

The international research panel included experts on medical ethics, on science, and clinical research. They were truly an eminent and very dedicated group. We met three times. We will publish the proceedings of that panel. This panel hailed from many countries, including Argentina, Brazil, China, Egypt, Guatemala, India, Russia, Uganda, Belgium, and the United States.

The panel has reported its findings and recommendations to the full commission in the form of a report entitled, "Research Across Borders." This will be published in the Federal Register, and we look

forward to taking public comment on it for 30 days, once it is published. The panel report will also be on our website as of this afternoon.

Christine Grady and Nelson Michael will report to us this morning on the panel and its work. But before we get underway, I would just like to ask if Jim Wagner wants to say a few words.

DR. WAGNER: I think you've covered it all; let's get underway.

DR. GUTMANN: Okay. We're going to get underway. So, this first session is on human subjects protection, as this whole day's meeting will be on. And, as many of you know, our work on human subjects protection dovetails nicely with the reform work already underway by the U.S. Government.

The Advanced Notice for Proposed Rulemaking released last month reflects many of the concerns -- not all, but many -- that we have heard in our prior meetings, and the public comments submitted to us about the current human subjects protection system, let us call it. I use the word "system" loosely, because it is a web of rules and regulations.

I think we will hear about this in a moment.